510(k) SUMMARY
(as required by 807.92(c))

FEB 11 2014

Regulatory Correspondent:
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Date of Summary: January 31, 2014

Trade/Proprietary Name: Guava II

Classification Name: Class II

Product Code: DPS and DSH

Regulation: 870.2340

Intended Use:
Guava II is intended to be used by cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multilead ECG devices. Guava II is intended to be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems. Guava II includes an algorithm that will analyze the 12 Lead ECG and produce measurements of the ECG recording as well as textual interpretation. The product also includes an automatic analysis and interpretation software library that provides ECG signal processing and analysis on a beat by beat basis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis for up to twelve (12) leads of historic ambulatory ECG data. The Guava II algorithm analysis can detect and classify arrhythmias and may be used to triage data, however, Guava II is not intended to offer independent diagnosis or provide medical alarms. Clinical judgment and experience are

used to check and interpret the data as part of a diagnosis. Guava II is not for use in life-supporting or sustaining systems or EGG monitoring devices. Guava II is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate.

Device Description:
The Guava II is a medical device software with a formal Application Programming Interface (API). The API can be invoked from Host Applications to provide services for capturing, storing, retrieving, viewing, editing, and analyzing ECGs (1-, 2-, 3-Channel and 12-Lead) and other Biosignals. Guava II may also be licensed to 3rd party organizations interested in embedding the capabilities within their own products. When the Guava II is used in other medical products, manufacturers will identify the indications for use depending on the application of their device.

The Guava II is not a life-supporting or life-sustaining system. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

Predicate Device(s): GlobalCardio (K111320)
Monebo Automated ECG Analysis and Interpretation Software Library (K062282)

Guava II has the same classification information, the same performance safety, the same design principle, similar intended use and technological characteristics, similar product design and specifications, similar effectiveness, and similar function as compared to the predicate devices.

Guava II represents, specifically, the subset of the functionality embedded within the predicate GlobalCardio (K111320) - Guava, the predecessor of Guava II, which is the subject of this 510(k) application.

GlobalCardio makes full use of the Guava functionality to capture and manage ECG's - the same functionality found in Guava II. Beyond that, GlobalCardio contains additional functionality outside the scope of ECG processing such as Patient Management, System Administration, Device Inventory Control, Cardiac Rehabilitation Data Management, etc. These are capabilities of the predicate device that are not contained in Guava II.

Guava II extends its predecessor, Guava, through the inclusion of features such as;

- The integration of the Monebo Automated ECG Analysis and Interpretation Software Library (K062282) for use in analysis and triage.
- Technological enhancements such as a "globalization" capability to simplify the translation of the software user interface into other languages.
- The ability to run on current software platforms.
- Incremental features such as the storage of the raw input data (e.g. audio waveform) into the ECG representation.
- And support for additional annotation types.

The Guava II also contains a version of the QRS Louvain Algorithm; which is also embedded within the GlobalCardio predicate. The Guava II Louvain Data Processor performs automated ECG analysis and interpretation in the same manner as GlobalCardio. The two products use the identical machine code library (DLL) to perform the analysis, and testing demonstrates the QRS Algorithm embedded in the Guava II Louvain Data Processor is identical in function to the QRS Algorithm embedded in GlobalCardio.

All other features of Guava II are present in at least one of the predicate devices. Therefore, the proposed Guava II device is substantially equivalent to GlobalCardio (K111320) and Monebo Automated ECG Analysis and Interpretation Software Library (K062282).

Performance Testing:
The device complies with AAMI EC11 and AAMI EC38 standards. Verification and validation activities related to the device modification were performed on the applicant device, and the predetermined acceptance criteria were met in all cases. The activities included scenario validations, algorithm confirmation testing, and device functional testing.

Conclusion:
The proposed device is substantial equivalent to the GlobalCardio (K111320) Monebo Automated ECG Analysis and Interpretation Software Library (K062282) devices. The proposed device has a similar intended use, technological, and design characteristics as the predicate device. Any minor differences do not introduce new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

February 11, 2014

Cardiocomm Solutions, Inc.
Jonathan Ward
962 Allegro Lane
Apollo Beach, FL 33572 US

Re: K122632
Trade/Device Name: Guava II
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DSH
Dated: October 25, 2013
Received: August 29, 2012

Dear Jonathan Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K122632

Device Name: Guava II

Guava II is intended to be used by cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multilead ECG devices. Guava II is intended to be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems. Guava II includes an algorithm that will analyze the 12 Lead ECG and produce measurements of the ECG recording as well as textual interpretation. The product also includes an automatic analysis and interpretation software library that provides ECG signal processing and analysis on a beat by beat basis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis for up to twelve (12) leads of historic ambulatory ECG data. The Guava II algorithm analysis can detect and classify arrhythmias and may be used to triage data, however, Guava II is not intended to offer independent diagnosis or provide medical alarms. Clinical judgment and experience are used to check and interpret the data as part of a diagnosis. Guava II is not for use in life-supporting or sustaining systems or EGG monitoring devices. Guava II is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2014.02.11 16:23:45 -05'00'